LESspine
Less Exposure Surgery Technologies

DORADO® E-LIFT® Intervertebral Body Fusion Device Instructions for Use

IMPORTANT NOTE TO OPERATING SURGEONS

Interbody fusion should only be undertaken after the surgeon has had hands-on training in these methods of spinal fixation, and has become thoroughly knowledgeable about spinal anatomy and biomechanics. Surgical technique manuals are available for detailed instructions on the correct use of the **DORADO® E-LIFT® Intervertebral Body Fusion Device**. The contents of these manuals are not adequate for complete instruction in the use of these systems. Even for surgeons already experienced in spinal instrumentation and interbody fusion procedures, new skills may be required that are best learned by working with an experienced surgeon or through a course of formal instruction with laboratory training. Lack of experience or expertise with these implants may result in complications.

Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

DESCRIPTION

The **DORADO® E-LIFT® Intervertebral Body Fusion Device** is part of the **LESspine® Lumbar IBF System**. The **DORADO® E-LIFT® Intervertebral Body Fusion Device** is intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolithesis at the involved level(s). The LESspine® E-LIFT® Intervertebral Body Cage is intended to be used with supplemental spinal fixation system(s) (Example: Posterior Pedicle Screw).

The implants are provided in a straight configuration only. Implants are offered with fixed footprints of 8x24mm and 9x30mm, and vary in height from 8mm – 14mm, in 1mm increments. The devices have features on the superior and inferior surfaces to resist device expulsion. The devices have axial and lateral windows for bony growth. Predicate devices are described in the same manner.

The **DORADO® E-LIFT® Intervertebral Body Fusion Device** components are supplied non-sterile, are single use, and are fabricated from PEEK-OPTIMA® LT1®with tantalum markers for radiographic visualization.

STERILIZATION

The **DORADO® E-LIFT® Intervertebral Body Fusion Device** implants are provided non-sterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines listed below. Implants are single-use devices, thus do not clean or re-sterilize an implant that has been in contact with or contaminated by blood or other infectious substances. The manufacturer and distributor assume no responsibility for cleaning and re-sterilization of implants, components, or reusable instruments performed by the individual or hospital.

LESspine® DORADO® E-LIFT® Intervertebral Body Fusion Devices are supplied clean and not sterile. ISO 8828 or AORN recommended practices for in-hospital sterilization to meet an SAL of 10-6 should be followed for all components.

User Sterilization Guidelines for Non-Sterile Implants

All devices should be positioned to allow sterilant to come in contact with all surfaces. Care should be taken to protect implants from mechanical damage. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected steriliza¬tion cycle specifications listed below:

RECOMMENDATIONS FOR STEAM STERELIZATION	
Sterilizer Type	Pre-Vacuum
Minimum Temperature	270°F (132°C)
Exposure Time	4 Minutes
Minimum Dry Time	20 Minutes

CLEANING AND DECONTAMINATION

Instruments are to be disassembled as needed according to CI-04-00001 "E-LIFT® System Assembly/Disassmbely Instructions for Cleaning" and cleaned according to CI-99-00001 "LESspine Cleaning Instructions - Instruments" prior to sterilization and introduction into the sterile surgical field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be decontaminated and cleaned prior to sterilization and reintroduction into a sterile surgical field. All devices should be positioned to allow sterilant to come in contact with all surfaces.

INDICATIONS

The **DORADO® E-LIFT® Intervertebral Body Fusion Device** is intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolithesis at the involved level(s).

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The **DORADO® E-LIFT® Intervertebral Body Fusion Device** is intended to be used with supplemental spinal fixation system(s) cleared for use in the lumbar spine.

CONTRAINDICATIONS

Use of implants is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, prior fusion at the level(s) to be treated, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.

Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implants. Patients with severe obesity, osteopenia, or degenerative diseases may place excessive stresses on bone and implants and may be at higher risk of implant failure.

Conditions that reduce the likelihood of successful fusion, such as radio- or chemotherapy for cancer, kidney dialysis, or osteopenia are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.

Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, lifestyle may interfere with their ability to follow post operative restrictions and who may place undue stresses on the implant during bony healing and may be of higher risk of implant failure.

PREOPERATIVE

1. **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery, and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and may loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration of the devices and damage to nerves or blood vessels.
2. Only patients that meet the criteria described in the indications should be selected.
3. Patient condition and/or pre dispositions such as those addressed in the aforementioned contraindications should be avoided.
4. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
5. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
6. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the device to verify that all parts and necessary instruments are present before surgery begins. The **DORADO® E-LIFT® Intervertebral Body Fusion Device**-components (described in the DESCRIPTION section) are not be combined with the components from another manufacturer.
7. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.
8. Before use, instruments and implants should be visually inspected and function should be tested to assure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, are cracked or have other irregularities, DO NOT USE!
9. Before use, all instruments are to be checked for debris, or other foreign contaminants. If any instruments or implants are observed to have any foreign debris or other contami¬nants, the entire convenience kit is to be returned to central processing for cleaning per the listed instructions. DO NOT USE!

PATIENT POSTOPERATIVE ACTIVITIES

The surgeon should inform the patient of the following postoperative activities:
1. The surgeon should inform the patient of the seriousness of the procedure performed and the limitation of the device implanted. The surgeon should also instruct the patient on how to properly recovery during the fusing process (i.e. range of motion, limiting physical activities, etc.).
2. The surgeon should instruct the patient on the amount of time after surgery of any weight bearing activities. Weight bearing activities performed before fusion occurs may cause some of the following: implant expulsion, breaking of the implant, prevent proper healing/non-union.
3. The patient should be immobilized until a fusion occurs. If the patient is not properly immobilized this could delay healing which could lead to non-union, implant expulsion, implant breakage, etc.
4. Patients should be instructed not to smoke, consume alcohol, or consume non-steroidals and aspirin, as determined by the surgeon. Patients should follow all surgeon postoperative activities and follow ups.
5. Implant should be revised or removed if appropriate for the following conditions: Non-union, pseudarthrosis, fractured implant, if the implant expels from the disc space, or if the surgeon determines the implant needs to be revised or removed for other reasons.

Following are specific warnings, precautions and adverse affects which should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects which can occur with surgery in general, but are important considerations particular to devices such as internal fixation implants and interbody fusion implants. General surgical risks should be explained to the patient prior to surgery.

WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS CONCERNING SPINAL FIXATION IMPLANTS

WARNINGS

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOAD ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to material fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of important failure.

3. MAGNETIC RESONANCE (MR) The **DORADO® E-LIFT® Intervertebral Body Fusion Device System** has not been evaluated for safety and compatibility in the MR environment. The **DORADO® E-LIFT® Intervertebral Body Fusion Device System** has not been tested for heating or migration in the MR environment.

4. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
a. **Previous Spinal Surgery:** Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
b. **The patient's weight.** An overweight or obese patient can produce loads on the device which can lead to failure of the appliance and the operation.
b. **The patient's occupation or activity.** If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, or repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
d. **A condition of senility, mental illness, alcoholism, or drug abuse.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
e. **Certain degenerative diseases.** In some cases, the progression of degenerative disease may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
f. **Foreign body sensitivity.** The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
g. **Smoking.** Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

PRECAUTIONS

1. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
2. **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery, and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and may loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration of the devices and damage to nerves or blood vessels.

POSSIBLE ADVERSE EFFECTS WITH THE DORADO® E-LIFT® Intervertebral Body Fusion Device

1. Nonunion, delayed union.
2. Bending or fracture of implant. Loosening of the implant.
3. Material sensitivity or allergic reaction to a foreign body.
4. Infection, early or late.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, or abnormal sensations due to the presence of the device.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paresthesia.
8. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the late post-operative period.
9. Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
10. Bursitis.
11. Paralysis.
12. Death.
13. Spinal cord impingement or damage.
14. Fracture of bony structures.
15. Reflex sympathetic dystrophy.
16. Degenerative changes or instability in segments adjacent to fused vertebral levels.

Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

LIMITED WARRANTY AND DISCLAIMER:
LESSPINE® PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

TO OBTAIN SURGICAL TECHNIQUE, MANUALS OR IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION AND THE DATE OF CONSULTATION, CONTACT LESSPINE®, FOR CURRENT INFORMATION.

FURTHER INFORMATION:
In case of complaint, or for supplementary information, or further directions for use of this system, please see the address on this page.

Customer Service Department
LESspine Innovations
350 Main Street
2nd Floor
Malden, MA 02148 U.S.A.
P + 1 978 232 3990 F + 1 978 232 3991

IFU-04-00001 Rev C